

Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 5

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cancer which is progressing in stage and a decrease in any one of the measured levels of Lung Specific Gene versus the levels of Lung Specific Gene in the control is associated with a cancer which is regressing in stage or in remission and wherein the Lung Specific Gene comprises SEQ ID NO: 2, 3, 4, 5, or 6.

6. (amended) The method of claim 1, 2, 3, 4, or 5 wherein the Lung Specific Gene comprises SEQ ID NO: 3 or 6.

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REMARKS

Claims 1-6 are pending in the instant application. Claims 1-6 have been rejected. Claims 1, 2, 3, 4, 5, and 6 have been amended. No new matter has been added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 1-6 under 35 U.S.C. § 112, second paragraph *b/c*

Claims 1-6 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point

Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 6

out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, with respect to claims 1-6, the Examiner suggest that the recitation of the term "LSG" is ambiguous. Therefore, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims by replacing the term "LSG" with --Lung Specific Gene-- in accordance with the definition in the instant specification at page 3.

With respect to claims 1-5, the Examiner suggests that the exact source of the sample of cells, tissue or bodily fluids must be clarified. Applicants respectfully disagree as the source, either patient or control, is made clear throughout these claims. However, in earnest effort to advance the prosecution, Applicants have also clarified in the comparison step of each claim that the measured level of Lung Specific Gene **in the patient** is compared to levels in a control.

With respect to claims 4-5, the Examiner suggests that recitation of the term "periodically" is imprecise as to how often the procedure is to take place. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to delete this term.

Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 7

Withdrawal of these rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested in light of the amendments to the claims and the above arguments.

II. Rejection of Claims 1-6 under 35 U.S.C. § 102(b)

Claims 1-6 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Cohen et al. The Examiner suggests that Cohen et al. teaches the use of LU103, a protein found in the lung, for the detection, diagnosis, staging, monitoring, prognosticating, prevention or treatment, and determination of individuals predisposed to conditions such as lung cancer. Further, the Examiner suggests that Cohen et al. teaches a protein that is identical to LSG, as determined by sequence homology, but is identified by a different name.

Applicants respectfully traverse this rejection.

At the outset, it is respectfully pointed out that the priority date of the instant application is May 21, 1998. Accordingly, Cohen et al. (U.S. Patent 5,939,265) which issued August 17, 1999, did not publish more than one year before the filing date of the instant application. Thus, rejection of the instant claims under 35 U.S.C. § 102(b) over the teachings of Cohen et al. is improper.

Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 8

However, the filing date of Cohen et al. is November 5, 1997 and therefore is potentially a prior art reference under 35 U.S.C. § 102(e). Therefore in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to state that the Lung Specific Gene comprises SEQ ID NO: 2, 3, 4, 5, or 6. As none of these Lung Specific Genes are taught or suggested by Cohen et al. this reference can not anticipate the claims as amended.

It is therefore respectfully requested that this rejection under 35 U.S.C. § 102(e) be withdrawn.

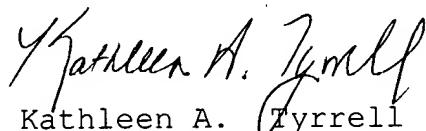
III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 9

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**VERSION WITH MARKINGS TO SHOW CHANGES MADE.**"

Respectfully submitted,



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Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 10

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 1-6 are amended as follows:

1. (amended) A method for diagnosing the presence of lung cancer in a patient comprising:

(a) measuring levels of LSG Lung Specific Gene in a sample of cells, tissue or bodily fluid obtained from the patient; and
(b) comparing the measured levels of LSG Lung Specific Gene in the patient with levels of LSG Lung Specific Gene in a sample of cells, tissue or bodily fluid obtained from a control, wherein an increase in measured levels of LSG Lung Specific Gene in the patient versus the LSG Lung Specific Gene levels in the control is associated with the presence of lung cancer and wherein the Lung Specific Gene comprises SEQ ID NO: 2, 3, 4, 5, or 6.

2. (amended) A method of diagnosing metastatic lung cancer in a patient comprising:

(a) measuring levels of LSG Lung Specific Gene in a sample of cells, tissue, or bodily fluid obtained from the patient; and
(b) comparing the measured levels of LSG Lung Specific Gene in the patient with levels of LSG Lung Specific Gene in a sample

Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 11

of cells, tissue, or bodily fluid obtained from a control, wherein an increase in measured ESG Lung Specific Gene levels in the patient versus the ESG Lung Specific Gene levels in the control is associated with a cancer which has metastasized and wherein the Lung Specific Gene comprises SEQ ID NO: 2, 3, 4, 5, or 6.

3. (amended) A method of staging lung cancer in a patient comprising:

(a) identifying a patient suffering from lung cancer;
(b) measuring levels of ESG Lung Specific Gene in a sample of cells, tissue, or bodily fluid obtained from the patient; and
(c) comparing the measured levels of ESG Lung Specific Gene in the patient with levels of ESG Lung Specific Gene in a sample of cells, tissue, or bodily fluid obtained from a control, wherein an increase in the measured levels of ESG Lung Specific Gene versus the levels of ESG Lung Specific Gene in the control is associated with a cancer which is progressing and a decrease in the measured levels of ESG Lung Specific Gene versus the levels of ESG Lung Specific Gene in the control is associated with a cancer which is regressing or in remission and

Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 12

wherein the Lung Specific Gene comprises SEQ ID NO: 2, 3, 4, 5,
or 6.

4. (amended) A method of monitoring lung cancer in a patient for the onset of metastasis comprising:

- (a) identifying a patient having lung cancer that is not known to have metastasized;
- (b) periodically measuring LSG Lung Specific Gene levels in samples of cells, tissue, or bodily fluid obtained from the patient; and
- (c) comparing the periodically measured levels of LSG Lung Specific Gene in the patient with levels of LSG Lung Specific Gene in cells, tissue, or bodily fluid obtained from a control, wherein an increase in any one of the periodically measured levels of LSG Lung Specific Gene in the patient versus the levels of LSG Lung Specific Gene in the control is associated with a cancer which has metastasized and wherein the Lung Specific Gene comprises SEQ ID NO: 2, 3, 4, 5, or 6.

5. A method of monitoring changes in a stage of lung cancer in a patient comprising:

Attorney Docket No.: **DEX-0113**
Inventors: **Yang et al.**
Serial No.: **09/700,770**
Filing Date: **January 16, 2001**
Page 13

(a) identifying a patient having lung cancer;

(b) ~~periodically~~ measuring levels of ESG Lung Specific Gene in samples of cells, tissue, or bodily fluid obtained from the patient; and

(c) comparing the measured levels of ESG Lung Specific Gene in the patient with levels of ESG Lung Specific Gene in a sample of the same cells, tissue, or bodily fluid of a control, wherein an increase in ~~any one of the~~ periodically measured levels of ESG Lung Specific Gene versus levels of ESG Lung Specific Gene in the control is associated with a cancer which is progressing in stage and a decrease in ~~any one of the~~ periodically measured levels of ESG Lung Specific Gene versus the levels of ESG Lung Specific Gene in the control is associated with a cancer which is regressing in stage or in remission and wherein the Lung Specific Gene comprises SEQ ID NO: 2, 3, 4, 5, or 6.

6. (amended) The method of claim 1, 2, 3, 4, or 5 wherein the ESG Lung Specific Gene comprises SEQ ID NO: ~~1,~~ 3 or 6.